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CERTIFICATE OF MAILING

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NOV. 1. 1999

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Henrik STENDER et al.

Serial No.: 08/943,777

Group Art Unit: 1643

Filed: October 3, 1997

Examiner: J. Fredman

For: NOVEL PROBES FOR THE DETECTION OF MYCOBACTERIA

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PETITION UNDER 37 CFR §1.182

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

A copy of the Notice attached to Paper No. 10 is enclosed.

Applicants hereby petition the Commissioner to waive the "Sequence Rules", 37 CFR §§1.831-1.825, with respect to the peptide nucleic acids, "PNA's", disclosed in the above application. Our check for \$130.00 for the petition fee is enclosed. Please charge our Deposit Account No. 07-1855 for any deficiency in any fee associated with this communication only.

The Sequence Rules are intended to apply to an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Rule 821(a). As will be explained in detail hereinafter, the PNA's described in the above application are not sequences of nucleotides, even though the PNA's do include nucleobases, such as thymine, cytosine, adenine or guanine. Nor are the PNA's "amino acid sequences" as that term is used in the Sequence Rules.

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STATEMENT OF FACTS

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110199/1658/35853.00001

PNA's have been described as compounds having a polyamide backbone and nucleobases depending therefrom via suitable ligands. See, e.g. WO 92/20702, discussed at page 23, line 24 of the present application.

The PNA's of the present invention likewise have a polyamide backbone or main chain, this backbone preferably comprising 6-30 polymerized moieties of formula (1) linked together by peptide bonds.

PNA's are not DNA's, because DNA's comprise a nucleobase linked to a ribose moiety to form a nucleoside, with the nucleosides being linked together by phosphate diester linkages to form DNA's. As can be seen from the present application, such as at page 17, lines 8-15. PNA's do not contain any ribose moiety, and hence do not contain any nucleosides, and, further, PNA's do not contain any phosphate diester linkages.

Clearly, then, the PNA's are not "nucleotides" and hence it is not possible to provide any "nucleotide sequence" listing. Applicants are concerned that the provision of a nucleotide sequence list would give rise to the PNA's being mistakenly characterized as a oligonucleotide (DNA).

With respect to the requirement in the Sequence Rules for amino acid sequence listings, the 6-30 polymerized moieties that form the backbone of the PNA's are not "L amino acids, commonly found in naturally occurring proteins...", and hence are outside the Sequence Rules. See Rule 821(a)(2).

Applying the Sequence Rules to the PNA's described in the above application would be like trying to fit a round peg into a square hole. The sequence listing at best would be a string of unknown amino acids, Xaa, that would convey no useful information, and a "features table" that would explain in a cumbersome manner 6-30 polymerized moieties. Just as the Sequence Rules "are not intended to encompass the subject matter generally referred to as synthetic resins", MPEP 2422.01, despite these resins including a string of amino acids, so too the PNA's are outside the Sequence Rules, since they are polyamide polymers closer to synthetic resins than DNA or proteins.

Adequate information already exists in the above application to enable the Office to conduct a search rapidly and efficiently. Applying the Sequence Rules to this application would serve no useful purpose but would impose an undue burden on Applicants.

It is recognized that a sequence listing has been filed for unmodified DNA sequenced embraced by SEQ ID NOS 1-123. This petition is directed to modified sequences embraced by the PNA probes of the invention.

RELIEF REQUESTED

As is apparent, the PNA's are unique and outside the Sequence Rules. It is therefore requested that the Commissioner waive the Sequence Rules with respect to the present application.

Respectfully submitted,

HENRIK STENDER ET AL.

By: GRAHAM & JAMES LLP

Per:



Vineet Kohli
Reg. No. 37,003
Attorney for Applicants

885 Third Avenue
New York, New York 10022
(212) 848-1065

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